

DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
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Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

February 1, 2023

Re: Animal Welfare Assurance A4051-01 [OLAW Case 1F]

Dr. Wayne Cascio Director of CPHEA US EPA – Research Triangle Park 109 TW Alexander Drive Durham, NC 27711

Dear Dr. Cascio,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 25, 2023 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the US Environmental Protection Agency, following up on an initial telephone report on January 24, 2023. According to the information provided, OLAW understands that following the conduct of experimental procedures, two mice were left on a transfer rack which was then sent to cage wash. The mice were in two separate cages and had access to water but not food for two days.

The immediate action taken upon discovery of the animals by the cage wash staff consisted of euthanizing the mice as they could not be returned to the colony due to biosecurity concerns. The Principal Investigator was contacted by the Institutional Animal Care and Use Committee (IACUC) and stated that the laboratory will be more vigilant to ensure that all animals are returned to the home cages following procedures. Cages will no longer be left on a transfer rack but will be stacked to ensure identification of any animals left in cages. The animal care staff will also conduct additional cage checks following the conduct of procedures to ensure that no animals are sent to cage wash.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken by the IACUC to investigate, correct and prevent recurrence of the noncompliance. Your prompt and thorough resolution of this matter is commendable and consistent with the PHS Policy on Humane Care and Use of Laboratory Animals philosophy of monitored self-regulation. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Axel Wolff, M.S., D.V.M.

Deputy Director

Office of Laboratory Animal Welfare

axel Wolf, ms, a

cc: IACUC Chair

A4051-1F



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

CENTER FOR PUBLIC HEALTH AND ENVIRONMENTAL ASSESSMENT Research Triangle Park, NC 27711

OFFICE OF RESEARCH AND DEVELOPMENT

January 25, 2023

Axel Wolff, M.S., D.V.M Deputy Director Office of Laboratory Animal Welfare National Institutes of Health

Dear Dr. Wolff:

We are writing to report the final resolution of an adverse animal welfare incident at the US EPA Research Triangle Park (RTP) research program, USDA Certificate number 55-F-0001, Customer ID number 962; PHS Assurance # D16-00569, A4051-01; AAALAC Unit #000509, including measures taken by the program to ensure that these events will not be repeated. A preliminary report of this event was originally communicated by telephone to OLAW on Tuesday, January 24.

On Friday afternoon, January 20, 2023, two researchers including the principal investigator were performing a procedure which required moving mice to a transfer rack, fasting the mice, and then moving them back to their home cages. Unfortunately, the researchers missed returning two mice in two separate cages from the transfer rack, and the rack was eventually sent to the cagewash room. The two mice spent the weekend in the cagewash room without food, although they did have water bottles. The animals were found Monday January 23 as cages were being dumped prior to washing, and they were humanely euthanized. Animals found in the cagewash room may not be returned to the general population. This event is an animal welfare issue which is considered noncompliance with PHS policy.

A quorum of the EPA-RTP IACUC met to discuss the situation today and resolved to request a plan for corrective actions from the Principal Investigator to ensure that this type of incident does not occur again. The PI promptly replied today with the following corrective actions:

- 1. The PI and lab staff will redouble their vigilance to ensure that all animals are returned to home cages from the transfer rack upon completion of the experiment.
- 2. To ensure that all animals are rehoused at their home cages, the PI and lab staff will remove the cages from the transfer rack and stack them for cleaning, rather than leaving them on the transfer rack, so that any animal inadvertently left behind will be identified promptly and placed in its correct home cage.

As a backup measure, animal care staff have already implemented additional checks for equipment and cages used by research staff to ensure there are no animals present before transfer to the cagewash room. The EPA-RTP IACUC believes that these measures will be effective in ensuring that no such incidents will be repeated in the future.

We hope these measures satisfactorily address the issues raised by this incident. Please contact Stephen Gavet (b) (6)

Animal Resources Program Office, if you have further questions.

Sincerely,

Wayne E. Cascio, M.D.

Wayne S Case No

Director, CPHEA Institutional Official

Stephen H. Gavett, Ph.D., D.A.B.T.

Stephen H. Lawett

CPHEA / PHITD / CIB EPA-RTP IACUC Chair

McCoy, Devora (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Thursday, January 26, 2023 11:14 AM

To:

Graff, Jaimie

Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: Final report of noncompliance, Assurance D16-00569

Good morning Jaimie,

Thank you for sending us this report and we will send an official response soon.

Best,

Devora

Devora McCoy, BS, MBA (pronunciation)
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390

Email: devora.mccoy@nih.gov

From: Graff, Jaimie < Graff. Jaimie@epa.gov> Sent: Thursday, January 26, 2023 8:17 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Gavett, Stephen <Gavett.Stephen@epa.gov>; Cascio, Wayne (he/him/his) <Cascio.Wayne@epa.gov>

(b) (6)

(b) (6)

Graff, Jaimie (b) (6)

(b) (6)

Subject: [EXTERNAL] Final report of noncompliance, Assurance D16-00569

Good morning;

Attached please find a final report of noncompliance for US EPA's ORD RTP animal care and use program, Assurance D16-00569, following a voicemail report on January 24, 2023.

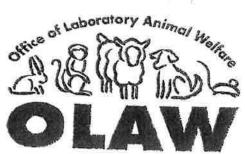
Please call or email me if you have any questions.

Thank you;

Jaimie Graff

Jaimie Graff, MA, CPIA | Director, Animal Resources Program Office | US EPA/ORM/RSCD/FRCB | Phone (b) (6)

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.



Initial Report of Noncompliance

By: Ou 1/24/23 Date: Time: /20 Name of Person reporting (b) (6) Telephone #: (b) Fax #: Email: Name of Institution: VS-EPA Assurance number: Did incident involve PHS funded activity? Funding component: Was funding component contacted (if necessary): What happened? Rack sent to engeneral my amounts on it, no part, did four write, Researchers Mongery eages Species involved: Personnel involved: Dates and times: Animal deaths: Projected plan and schedule for correction/prevention (if known): _

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #____